

1 Cabinet for Health and Family Services

2 Office of Health Policy

3 (New)

4 900 KAR 6:130. Certificate of Need criteria for physician exemption.

5 RELATES TO: KRS 216B.010, 216B.020, 216B.040, 216B.990

6 STATUTORY AUTHORITY: KRS 194A.030, 194A.050, 216B.040(2)(a)1

7 NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.040(2)(a)1 requires the

8 Cabinet for Health and Family Services to administer Kentucky's Certificate of Need

9 Program and to promulgate administrative regulations as necessary for the program.

10 This administrative regulation establishes the requirements for physician exemption

11 criteria necessary for the orderly administration of the Certificate of Need Program.

12 Section 1. Definitions. (1) "Ambulatory surgical center" is defined by KRS 216B.015.

13 (2) "Entity" means any legally recognized business entity in which an individual or
14 group may practice its profession including a professional limited liability company,
15 professional service corporation, partnership, or sole proprietor.

16 (3) "Evaluation and Management codes" means those codes recognized by the
17 American Medical Association as procedures involving evaluation of patients and
18 management of patient care in the Current Procedure Terminology® references.

19 (4) "Office" or "clinic" means the physical location at which health care services are
20 provided by a physician, dentist, advanced practice registered nurse, licensed clinical
21 social worker, speech therapist, occupational therapist, physical therapist,

1 psychologists, or other practitioner of the healing arts.

2 (5) "Owner" means a "person" as defined in KRS 216B.015(21) who is applying for
3 the certificate of need and will become the licensee of the proposed health service or
4 facility.

5 (6) "Practice" means the individual, entity, or group that proposes to provide health
6 care services and shall include the owners and operators of an office or clinic.

7 (7) "Practitioner of the healing arts" is defined in KRS 311.271.

8 (8) "Primarily" means a simple majority or something that occurs at least fifty-one
9 percent (51%) of the time.

10 (9) "Qualified academic medical center" means:

11 (a) An institution of higher education which operates an accredited medical school
12 within the Commonwealth of Kentucky;

13 (b) An institution, organization, or other entity which directly or indirectly owns or is
14 under common control or ownership with an accredited medical school operated within
15 the Commonwealth of Kentucky; or

16 (c) An individual, organization, entity, or other person which is qualified under
17 Section 501(c)(3) of the Internal Revenue Code (26 U.S.C. 501(c)(3)) as a result of
18 supporting or operating in support of an institution, organization, entity, or other person
19 referenced in paragraph (a) or (b) of this subsection.

20 Section 2. Physician non-exemption due to operation of an ambulatory surgical
21 center. (1) An office or clinic that is operating an ambulatory surgical center pursuant
22 to KRS 216B.095(7) is not exempt from the Certificate of Need requirements.

23 Section 2. Physician exemption from Certificate of Need. (1)(a) An office or clinic

that would otherwise be required to obtain a Certificate of Need is exempt from
Certificate of Need pursuant to KRS 216B.020(2) if:

1. The practice claiming the exemption is 100 percent owned in an organizational
form recognized by the Commonwealth as one in which the listed professions can be
practiced by the individual physician, dentist, advanced practice registered nurse,
licensed clinical social worker, speech therapist, occupational therapist, physical
therapist, psychologist, or other practitioner of the healing arts or group of physicians,
dentists, or advanced practice registered nurses, licensed clinical social workers,
speech therapists, occupational therapists, physical therapists, psychologists, or other
practitioners of the healing arts (hereinafter collectively referred to as "physician")
claiming the exemption;

2. The practice claiming the exemption primarily provides physician services (e.g.,
evaluation and management codes) rather than services or equipment covered by the
State Health Plan;

3. Services or equipment covered by the State Health Plan which are offered or
provided at the office or clinic shall be primarily provided to patients whose medical
conditions are being treated or managed by the practice;

4. A physician or physicians licensed to practice and practicing in Kentucky within
the practice and claiming the exemption are responsible for all decisions regarding the
care and treatment provided to patients;

5. Patients are treated on an outpatient basis and are not maintained overnight on
the premises of the office or clinic;

6. Services or equipment covered by the State Health Plan that are offered or

provided at the office or clinic are related to the professional services offered to patients of the practice claiming the exemption;

7. Major medical equipment in excess of the limits set forth in 900 KAR 6:030 is not being utilized without a Certificate of Need or other statutory or regulatory exemption; and

8. Nothing in this section shall limit or prohibit the continued operation of an office or clinic that was established and in operation prior to January 31, 2006, and operating pursuant to and in accordance with the following:

a. Provisions of a Certificate of Need advisory opinion issued by the Office of Health Policy specifically with respect to an identified office or clinic that sought the opinion;

b. Provisions of an Attorney General opinion issued specifically with respect to that office or clinic; or

c. An order issued with respect to that office or clinic by a court of competent jurisdiction in the Commonwealth of Kentucky.

(b) A practice owned entirely by a radiologist or group of radiologists shall demonstrate the following:

1. Compliance with paragraphs (a)1, 4, 5, and 6 of this subsection;

2. The radiologists shall regularly perform physician services (e.g., test interpretations) at the location where the diagnostic tests are performed, including interpretations by or through teleradiology; and

3. The billing patterns of the practice indicate that the practice is not primarily a testing facility and that it was organized to provide the professional services of radiology.

(c) An office or clinic owned and operated by a Qualified Academic Medical Center shall demonstrate the following:

1. The physician or physicians providing care and treatment to the patients of the office or clinic shall be licensed to practice in Kentucky and shall be employed by the Qualified Academic Medical Center; and

2.a. The office was established and in operation prior to January 31, 2006;

b. The office does not provide any services or equipment covered by the State Health Plan; or

c. At the time the office began providing care and treatment to patients, it was not located in a county designated as a Metropolitan Statistical Area as defined by the U.S. Office of Management and Budget, and there is a documented agreement of support or collaboration between the Qualified Academic Medical Center and each existing hospital in the county in which the office is located.

Section 3. Physician non-exemption due to operation of an ambulatory surgical center. An office of clinic that is operating an ambulatory surgical center pursuant to KRS 216B.095(7) is not exempt from Certificate of Need.

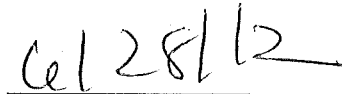
900 KAR 6:130

This is to certify that the Executive Director of the Office of Health Policy has reviewed and recommended this administrative regulation prior to its adoption, as required by KRS 156.070(4)

APPROVED:

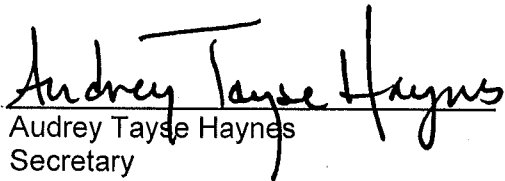


Carrie Banahan
Executive Director
Office of Health Policy

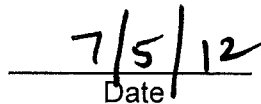


Date

APPROVED:



Audrey Tayse Haynes
Secretary
Cabinet for Health and Family Services



Date

900 KAR 6:130

PUBLIC HEARING AND COMMENTS:

A public hearing on this administrative regulation shall, if requested, be held on August 21, 2012, at 9:00 a.m. in the Public Health Auditorium located on the First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by August 14, 2012, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be cancelled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business August 31, 2012. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Jill Brown, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40601, Phone: 502-564-7905, Fax: 502-564-7573

REGULATORY IMPACT ANALYSIS AND TEIRING STATEMENT

Administrative Regulation Number: 900 KAR 6:130

Contact Person: Carrie Banahan or Chandra Venettozzi, (502) 564-9589

1. Provide a brief summary of:
 - (a) What this administrative regulation does: This administrative provides clarification related to physician exemption from Certificate of Need. Language related to this subject was formerly included in 900 KAR 6:090 – Certificate of Need hearing and show cause hearing and is being moved to a separate administrative regulation for clarity. Also, as a result of the passage of House Bill 458, language was added to clearly state that physician owned ambulatory surgery centers are not exempt from Certificate of Need.
 - (b) The necessity of this administrative regulation: This administration regulation is necessary to provide clear and concise information related to physician exemption from the Certificate of Need program.
 - (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to KRS 216B.010, 216B.020, 216B.040, 216B.990 by providing clear and concise information related to physician exemption from the Certificate of Need Program.
 - (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation will provide clear and concise information related to physician exemption from the Certificate of Need Program.
2. If this is an amendment to an existing administrative regulation, provide a brief summary of:
 - (a) How the amendment will change this existing administrative regulation: This is a new administrative regulation.
 - (b) The necessity of the amendment to this administrative regulation: This is a new administrative regulation.
 - (c) How the amendment conforms to the content of the authorizing statutes: This is a new administrative regulation.
 - (d) How the amendment will assist in the effective administration of the statutes: This is a new administrative regulation.
3. List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation will affect health care providers governed by the Certificate of Need law, citizens who use health care in Kentucky, health planners in the Certificate

of Need Program, and local communities that plan for, use, or develop community health care facilities. Approximately 160 applications for Certificate of Need are filed annually.

4. Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:
 - (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: The entities will have clear and concise information related to physician exemption from the Certificate of Need Program.
 - (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be no cost to entities to comply with this amendment.
 - (c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Entities meeting the exemption status will not have to file an application for Certificate of Need.
5. Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:
 - (a) Initially: No cost
 - (b) On a continuing basis: No cost
6. What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: No funding is necessary since there is no cost to implementing this administrative regulation.
7. Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding is necessary.
8. State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish any fees and does not increase any fees either directly or indirectly.
9. TIERING: Is tiering applied? (Explain why or why not)
Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it. Disparate treatment of any person or entity subject to this administrative regulation could raise questions of arbitrary action on the part of the agency. The "equal protection" and "due process" clauses of the Fourteenth Amendment of the U.S. Constitution may be implicated as well as Sections 2 and 3 of the Kentucky Constitution.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 900 KAR 6:130 Contact Person: Carrie Banahan or Chandra Venettozzi

1. Does this administrative regulation relate to any program, service, or requirements of a state or local government (including cities, counties, fire departments, or school districts)?

Yes X No

If yes, complete questions 2-4.

2. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This amendment may impact any government owned, controlled or proposed healthcare facilities or services.
3. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. This administrative regulation is authorized by: KRS 216B.010, 216B.020, 216B.040, 216B.990
4. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. None.
- (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? No impact to revenues.
 - (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? No revenues will be generated to state or local government.
 - (c) How much will it cost to administer this program for the first year? None.
 - (d) How much will it cost to administer this program for subsequent years? None.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): None
Expenditures (+/-): None
Other Explanation: None